

Looking Beyond The Horizon

What's New for Drugs
and Public Policy

Brian Allen,
VP of Government Affairs

Current Challenges

- Opioids
- Compounded Medications
- Physician Dispensing
- Drug Price Inflation
- High-Cost Specialty “Wonder Drugs”
- Drug Cascading
- Other Drug Cost Drivers



Opioids

81.3
2012

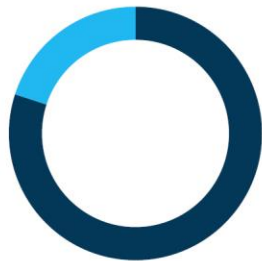
66.5
2016

Prescription rates per person
declining nationally

Opioid overdose deaths
increased in 2016

42,249
2016
all opioid deaths

17,087
2016
prescription opioid
deaths



80%

Of heroin users first abused
prescription opioids

Some Drug Manufacturers Don't Seem to Be Getting It...

From Reuters Health News
February 23, 2018 | 11:13am



KemPharm's Opioid Painkiller Gets FDA Approval, Shares Soar

"The company resubmitted the drug's marketing application for review in September after appealing against a rejection by the drug regulator in 2016 on concerns of opioid abuse."

"... expects to produce close to 5 billion tablets a year..."

Montana Statistics

119 Overdose
Deaths
in 2012

8th Lowest
Overdose
Rate in US, 2016



vs



12.9 *Montana overdose
death rate in 2012*

Compounded Medications

- Legitimate compounding withstands utilization review
- Questionable compounding involves high costs
- Pennsylvania Problem
- High-profile enforcement actions
 - June 2018: Florida
 - March 2018: Alabama



Examples of Expensive Compounds

April 2018



Gabapentin Powder

\$6,721 for 30-day supply

January 2018



Food Color Brown

\$249 for 30-day supply

May 2018



CAPSULE CONI-SNAP #3 OLIVE/CLEAR

\$337 for 120 capsules

August 2018

Office of Inspector General report found annual compound spending in Medicare Part D was **24x higher from 2010 to 2016**

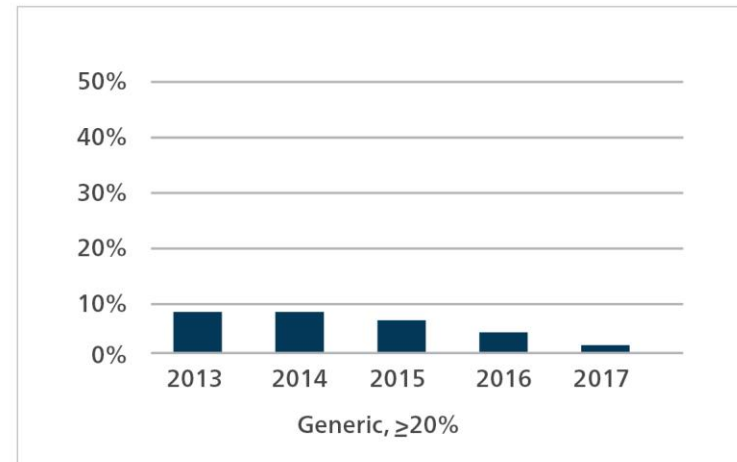
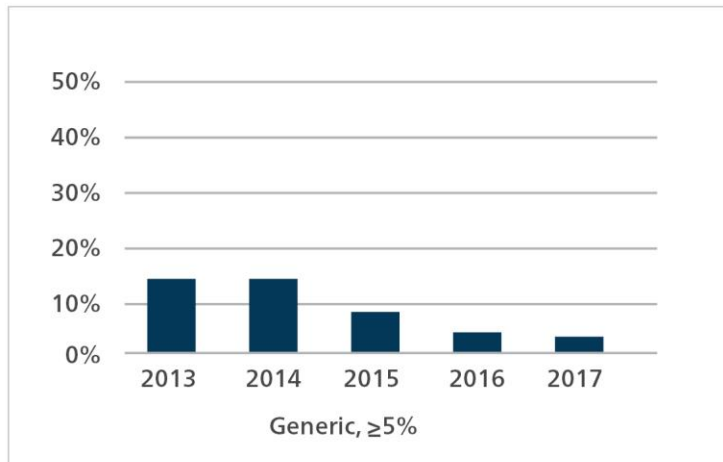
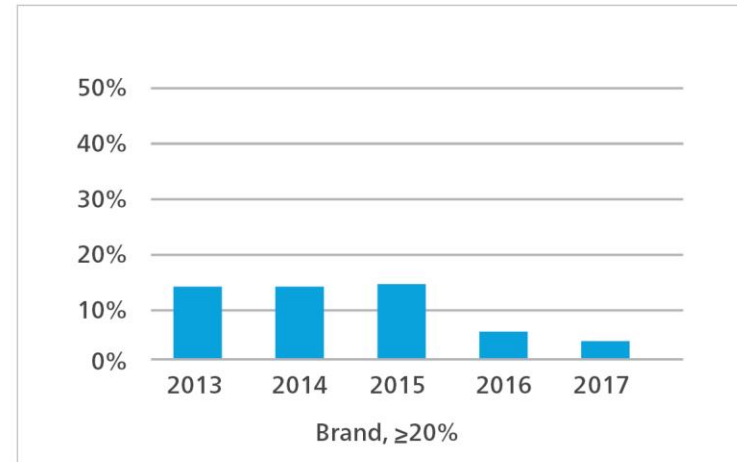
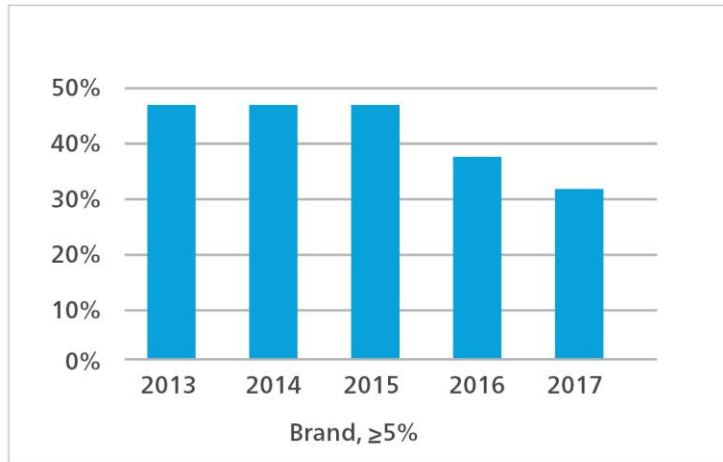
Physician Dispensing

- Most States Allow
- Repackaged Medications
 - Unique National Drug Code (NDC)
 - “Assigned” Average Wholesale Price
 - Circumvent Fee Schedules
- Laws to base reimbursement on AWP of original product
- “Boutique” drugs
- Montana Statute 37-2-104



Drug Price Inflation

Share of Prescription Drugs with Annual Price Increases, 2013-2017



Source: https://www.ahip.org/wp-content/uploads/2018/06/AHIP_IssueBrief_RxTransparency_62018FINAL.pdf

Drug Price Inflation

Evzio

\$575.00 **+652%** **\$3,750.00**
2014 ————— 2017

Wellbutrin XL

\$1,187.41 **+596%** **\$7,073.70**
2012 ————— 2017

Percocet

\$66.40 **+296%** **\$196.74**
2012 ————— 2017

Source: <https://www.ahip.org/then-vs-now/> Based on Redbook WAC pricing before discounts or rebates

High-Cost Specialty “Wonder Drugs”

95% Specialty Drugs

85% Orphan Drugs

>\$10,000
cost per patient per year



Alimta (Mesothelioma)
**\$3,400 per
500mg vial**



Harvoni (Hepatitis C)
**\$87,000 for
3mo supply**



Solvadi (Hepatitis C)
**\$71,000 for
3mo supply**



Truvada (Needle Stick)
**\$1,800 per
month**

Drug Cascading

- Prescribing additional drugs to treat side effects of primary drug
- Opioids
 - Market in 2016 = \$8.6 billion
 - Follow-on market expected to reach \$3 billion
- Ibuprofen
 - NSAID available OTC
 - Prolonged use can cause ulcers
 - Duexis brand = \$2300 for 90 tablets



Other Drug Cost Drivers

- Defensive prescribing
- Ineffective prescribing
 - Ex: Gabapentin and pregabalin for non-neuropathic pain
- Brand drug “ever-greening” and patent protection
 - Lyrica
 - Packaging
 - Allergan and Restasis



Strategies for Meeting the Challenges

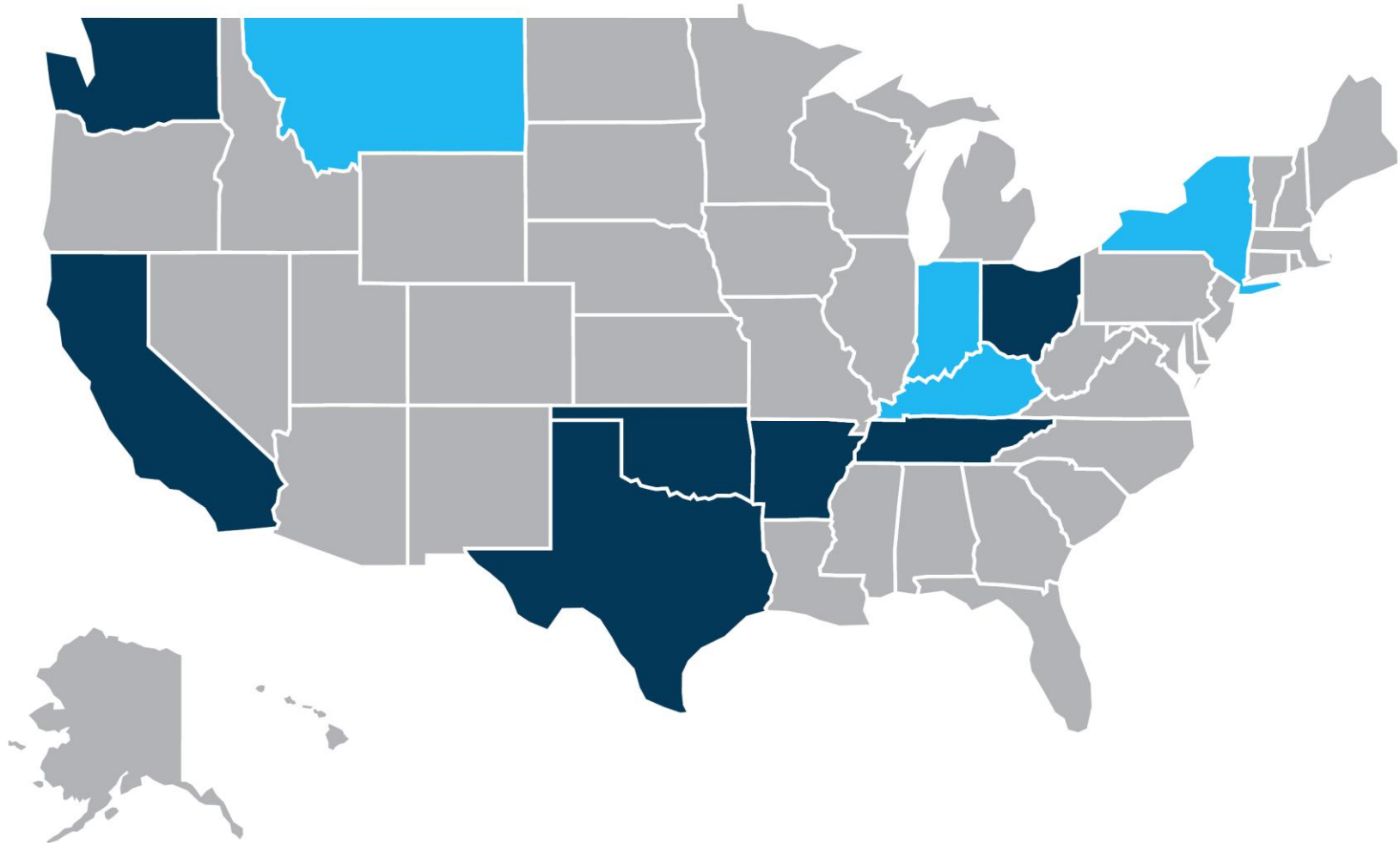


Drug Formulary

- List of preferred medications
- Supported by evidence-based guidelines
- Goal: ensure that injured workers receive most appropriate pharmacy care for injury
- Not only focused on opioids
- But can have significant impact on controlling use of problematic opioids



Drug Formularies in the United States



How Does a Drug Formulary Work?

- Alignment with treatment guidelines
- “Y” Status Drugs: do not require prior authorization
- “N” Status Drugs: may be prescribed with prior auth based on demonstration of medical necessity



How Does a Drug Formulary Work?

- “Y” Drugs and pre-authorized “N” Drugs dispensed at pharmacy without delay
- Drugs outside treatment guidelines or without prior auth held at pharmacy and reviewed by claims admin.
- “N” status is not a “locked gate”, but a “speed bump”



Drug Formulary Addressing Challenges

Opioids

ODG Guidelines require prior auth for most opioids



Texas

- Reduced # of long-acting opioids prescribed to injured workers
- Number of claims receiving “N” drug opioids w/90+ MME’s per day decreased from almost **15,000 in 2009** to **<500 in 2015**

Drug Formulary Addressing Challenges



Compounded Medications

Most state formularies require prior authorization



Physician Dispensing

California requires physicians to obtain prior auth



Drug Price Inflation

Formulary can guide physician to lower cost but equally effective alternative



High-Cost Specialty “Wonder” Drugs

Formulary can help identify lower cost alternatives

Drug Formulary Addressing Challenges



Drug Cascading

Formulary + Guidelines can guide physician to alternative medications with fewer side effects



Defensive Prescribing

Formulary helps physicians choose medications recommended for specific condition or injury



Ineffective Prescribing

Formulary provides latest evidence-based recommendations



Ever-Greening and Patent Protection

Formulary can guide to acceptable generic alternatives

Opioid Prescribing Limits

- CDC Opioid Prescribing Guidelines
- State-mandated prescribing limits
 - Over half of states have adopted
- Montana does not yet have statutory prescribing limits
- Pushback from pain doctors and patients just starting to get organized



Marijuana As a Medicine



National Academies Study

“The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research” (2017)

- Considered More Than 10,000 Scientific Abstracts
- Nearly 100 Research Conclusions Organized Into:
 - Conclusive
 - Substantial
 - Moderate
 - Limited
 - No/Insufficient



National Academies Study

- Conclusive or Substantial Evidence
 - Effective for Treating Chronic Pain
 - Increased Risk of Motor Vehicle Accidents
- Moderate Evidence
 - Improving Short-Term Sleep Outcomes Impacted by Chronic Pain
 - Increased Risk of Overdose Injuries Among Pediatric Populations



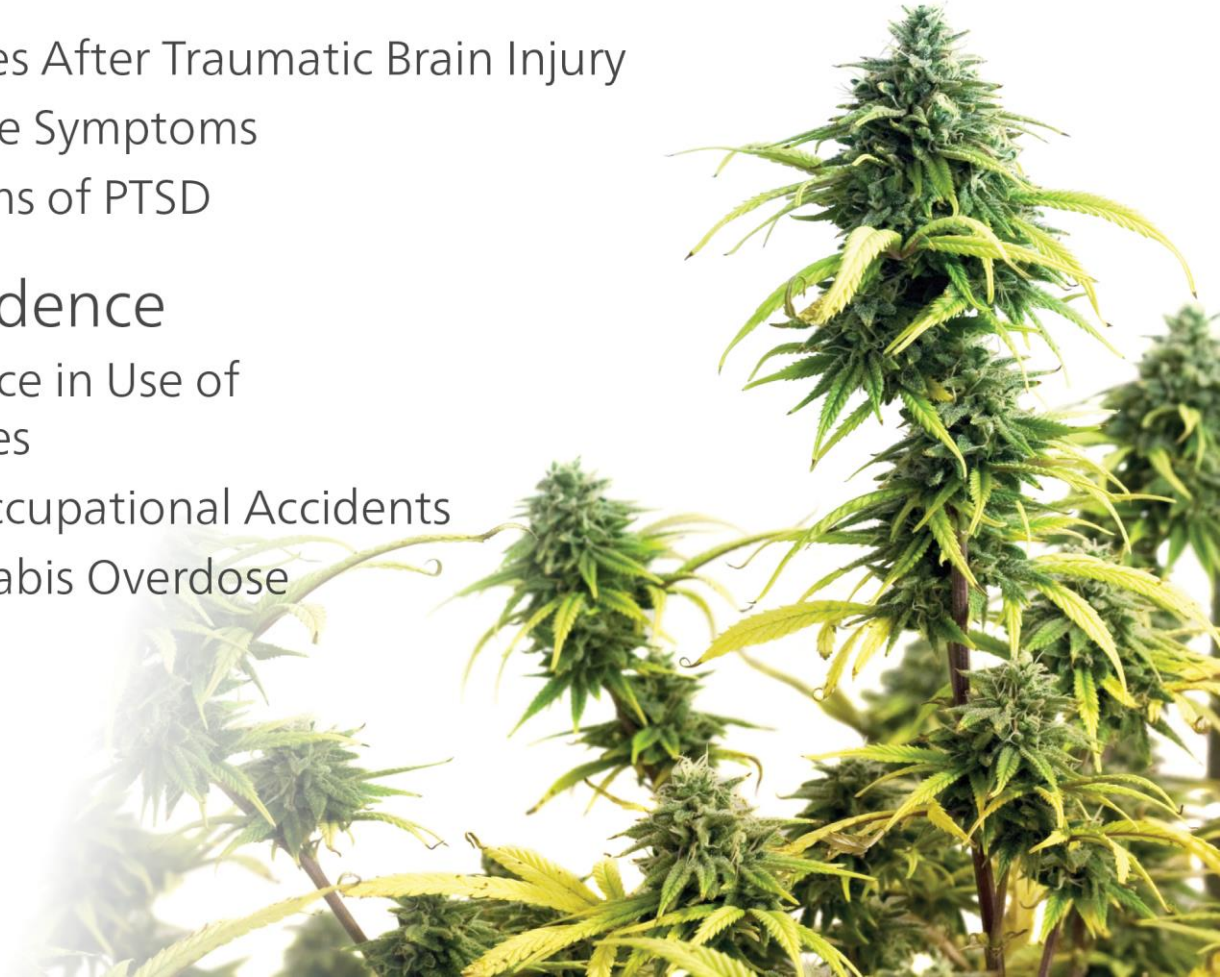
National Academies Study

- Limited Evidence

- Improving Outcomes After Traumatic Brain Injury
- Reducing Depressive Symptoms
- Improving Symptoms of PTSD

- No/Insufficient Evidence

- Achieving Abstinence in Use of Addictive Substances
- Increased Risk of Occupational Accidents
- Death Due to Cannabis Overdose



National Institute on Drug Abuse

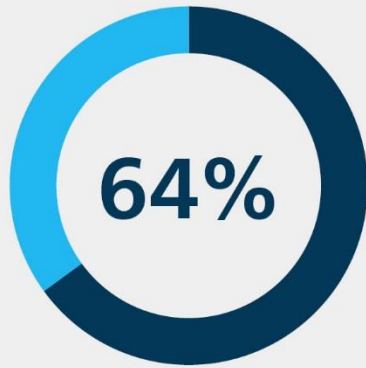
- Chemicals Show More Promise Than Using Whole Plant
- Some Marijuana-Based Medications Are FDA Approved to Treat:
 - Nausea in Cancer Patients
 - Neuropathic Pain in MS Patients
 - Childhood Epilepsy/Dravet Syndrome
- Little Known About Long-Term Effects
- Potential Adverse Effects Based on Other Health Conditions



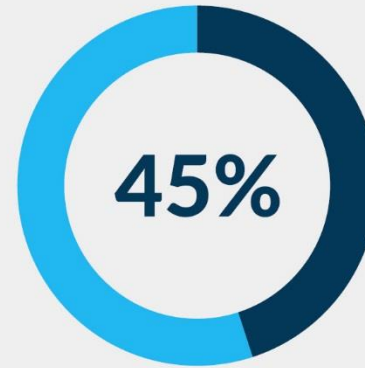
Marijuana as a Medicine

University of Michigan Study, 2013-2015

Surveyed 244 medical cannabis patients with chronic pain



Reported reduction in
use of opioids



Reported decreased side
effects and improved
quality of life

Marijuana as a Medicine

Bradford Study, published April 2018

Measured Medicare Part D opioid prescribing by states, 2010-2015

States with open
dispensaries



Reduction in opioid
prescribing

States with self-
cultivation



Reduction in opioid
prescribing

Marijuana As a Medicine

- Limitations in Research
- Two Active Chemicals:
 - **THC** - Pain Relieving Properties, Creates “High”
 - **CBD** - Impacts Brain Without High
- Around 400 Other Chemicals
 - Most Have Not Been Studied In Depth



Marijuana as a Medicine

- Most of What We Know is Anecdotal
- Limited Studies
- Little to No Controls
- Longitudinal Studies Underway



Workers' Compensation

- Employers and Carriers Caught in “Tug-o-War” Between State and Federal Law
- Evidence-Based Guidelines Do Not Include Medical Marijuana
- Making Rules as We Go



Marijuana: Road to Legality



2018

Utah, Oklahoma, South Dakota, Missouri and Kentucky considering ballot proposals to legalize medical marijuana

Possibilities



Possibilities



Other Policy Solutions



Drug Importation

- Celebrex 200mg
 - \$6.20 per pill estimated US cash price
 - \$0.53 per pill est. Canadian cash price
- Diclofenac 100mg
 - \$2.26 per pill estimated US cash price
 - \$0.43 per pill est. Canadian cash price
- Vermont Passed Drug Importation Legislation
- Utah, West Virginia & Oklahoma Attempted but Failed

Drug Costs

Intermountain Healthcare Leads Charge Against Rising Drug Costs

Hospital systems across U.S. join to make generic drugs

“... aims to help patients and hospitals facing drug shortages and increasing costs of certain medications and make them more available and more affordable....”

Pharmacogenomics

- Genetic profile to determine individual reaction to specific medication
- Aids in determining effectiveness or dosing
- Early success in psychotropic drugs
- Limitations in cost, testing, scope, reimbursement
- Ethical issues



Pharmacogenomics

Pharmacogenomic Testing a Success at South Dakota Health System

Driving down other costs helps offset financials when reimbursement is denied for pharmacogenomics testing

“Pharmacogenomics is a tool that helps clinicians to narrow their choices for medications from as many as 20 or more down to maybe eight to 12 medications. Such testing allows physicians to target the right medication for each patient while doing their best to avoid adverse effects.”

Krista Bohlen, PharmD

Director of Personalized Pharmaceutical Medicine
Avera Institute for Human Genetics

Emerging Technology

- 3D printing of medications
 - Spiritam only 3D-printed med approved by FDA
 - Changes nature of FDA approvals
- Virtual Care
 - Wearable technology to monitor vitals/blood chemistry
 - Alerts to physicians
 - Future AI advances
- Public policy significantly lagging behind technological advances



“The best way to predict the future is to create it.” Peter Drucker



Questions?

Thank you for your attendance and attention.

